

IN THE CLAIMS:

1. (Previously amended) An article of manufacture for human pharmaceutical use comprising:

- (a) an oral dosage form comprising a PDE5 inhibitor having an IC₅₀ for the inhibition of PDE5 less than 10 nM, and sufficient bioavailability to be effective in about 1 to about 10 mg unit oral dosages;
- (b) a package insert providing that the PDE5 inhibitor is useful to treat sexual dysfunction in a patient in need thereof by utilizing a chronic dosing regimen for at least three days; and
- (c) a container.

2. (Original) An article of manufacture for human pharmaceutical use comprising:

- (a) an oral dosage form comprising a PDE5 inhibitor having an IC₅₀ less than 10 nM, and a sufficient bioavailability to be effective in about 1 to about 10 mg unit oral dosages;
- (b) a package insert providing that the PDE5 inhibitor is useful to treat sexual dysfunction in a patient in need thereof by utilizing a chronic dosing regimen wherein the chronic dosing regimen improves vascular conditioning; and
- (c) a container.

3.-4. (Cancelled)

5. (Previously amended) The article of claim 1 or 2 wherein the PDE5 inhibitor further has
(i) at least a 100 fold differential in IC₅₀ values for the inhibition of PDE5 versus PDE6, and
(ii) at least 100 fold differential in IC₅₀ values for the inhibition of PDE5 versus PDE1c.

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6. (Previously amended) The article of claim 1 or 2 wherein the oral dosage form comprises about 1 mg, about 2 mg, about 5 mg, or about 10 mg, of the PDE5 inhibitor.

7. (Previously amended) The article of claim 1 or 2 wherein the chronic dosing regimen is a daily dosing regimen.

8. (Previously amended) The article of claim 1 or 2 wherein the chronic dosing regimen comprises administration of about 1 mg/day to about 10 mg/day of the PDE5 inhibitor.

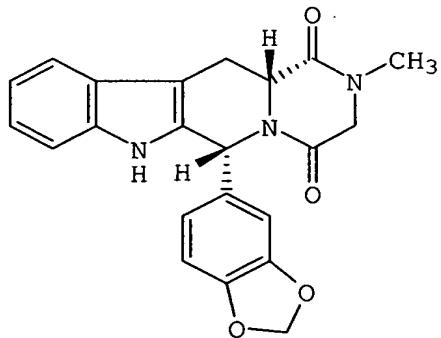
9. (Previously amended) The article of claim 1 or 2 wherein the package insert provides a maximum dosage of the PDE5 inhibitor of about 10 mg per day.

10. (Previously amended) The article of claim 1 or 2 wherein the PDE5 inhibitor is selected from the group consisting of (6R,12aR)-2,3,6,7,12,12a-hexahydro-2-methyl-6-(3,4-methylenedioxyphenyl)pyrazino[2',1':6,1]pyrido[3,4-b]indole-1,4-dione; and (3,4-methylenedioxyphenyl)pyrazino[2',1':6,1]pyrido[3,4-b]indole-1,4-dione.

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11. (Original) The article of claim 10 wherein the chronic dosing regimen comprises administration of about 1 mg/day to about 10 mg/day of the PDE5 inhibitor.

13. (Previously amended) The article of claim 1 or 2 wherein the PDE5 inhibitor has the structure



14.-18. (Cancelled)

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19. (Previously presented) An article of manufacture for human pharmaceutical use comprising:

(a) an oral dosage form comprising a PDE5 inhibitor having an IC₅₀ for the inhibition of PDE5 less than 10 nM, and sufficient bioavailability to be effective in about 1 to about 10 mg unit oral dosages;

(b) a package insert providing that the PDE5 inhibitor is useful to treat sexual dysfunction in a patient in need thereof by utilizing a chronic dosing regimen; and

(c) a container.

20. (Currently amended) An article of manufacture for human pharmaceutical use comprising:

(a) an oral dosage form comprising a PDE5 inhibitor having an IC₅₀ for the inhibition of PDE5 less than 10 nM, and a sufficient bioavailability to be effective in about 1 to about 10 mg unit oral dosages;

(b) a package insert providing that the PDE5 inhibitor is useful to treat sexual dysfunction in a patient in need thereof by utilizing a daily dosing regimen, and

(c) a container.

21. (New) The article of claim 1, 2, 19, or 20 wherein the sexual dysfunction is male erectile dysfunction.

22. (New) The article of claim 1, 2, 19, or 20 wherein the sexual dysfunction is female sexual arousal disorder.

23. (New) The article of claim 19 or 20
wherein the package insert provides a maximum dosage of
the PDE5 inhibitor of about 10 mg per day.

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